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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/777,566	02/05/2001	Jay M. Short	DIVER1370-6	4776

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EXAMINER	
RAMIREZ, DELIA M	
ART UNIT	PAPER NUMBER
1652	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/777,566	Applicant(s) SHORT ET AL.	
	Examin r Delia M. Ramirez	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 May 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-15* is/are pending in the application.

4a) Of the above claim(s) *14 and 15* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-13* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 February 2001* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☒ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1,8,9,11* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

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DETAILED ACTION

Status of the Application

Claims 1-15 are pending.

Applicant's election with traverse of Group I, claims 1-13 drawn in part to an expression system comprising a polynucleotide encoding the polypeptide of SEQ ID NO: 2, host cells and a method of producing the polypeptide of SEQ ID NO: 2, in Paper No. 13, filed on 5/28/2003 is acknowledged.

Applicant's traverse is on the ground(s) that examination of Groups I, II and claim 14 of Group III should not impose an undue burden on the Examiner since claims 12-14 depend either directly or indirectly from claim 1 and incorporate all the limitations thereof. As such, Applicants request the rejoinder of claims 1-14.

Applicant's arguments have been fully considered but are not deemed persuasive to overcome the restriction requirement. While it is acknowledged that the plant and the method of Group II use the expression system of Group I and the composition of Group III comprises the plant of Group II, each of these inventions is deemed patentable distinct. Furthermore, each of the inventions have a different class/subclass. Moreover, publications which disclose a polynucleotide encoding the polypeptide of SEQ ID NO: 2 may not disclosed information in regard to plants comprising said nucleotides, or compositions comprising said plants. Therefore, a complete search of claims 1-14 would require sequence, patented/non-patented literature, and different class/subclass searches which may not be necessarily overlapping or co-extensive.

The requirement is deemed proper and therefore is made FINAL.

Claims 14-15 are withdrawn from further consideration by the Examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

It is noted that some of the elected claims, i.e. 12-13, are still partially drawn to non-elected inventions. Examination of such claims will be restricted to the subject matter elected, which in the instant case is an expression system comprising a polynucleotide of SEQ ID NO: 2, host cells and a method of use of said expression system. Applicants are requested to amend the claims accordingly in response to this Office Action.

Specification

1. The specification is objected to because it contains blank spaces which correspond to the deposit number and the date when the deposit was made. See page 31, lines 20-21. It is also noted that the address of the American Type Culture Collection is incorrect. Appropriate correction is required.

2. The abstract of the disclosure is objected to due to the recitation of "A purified recombinant phytase enzyme derived from E. coli B. The enzyme has...". As written, it is unclear as to how the first sentence is connected with the remainder of the text. Appropriate correction is required.

Priority

3. Acknowledgment is made of a claim for domestic priority under 35 U.S.C. 120 or 121 to US application No. 09/318,528 filed on 05/25/1999, 09/291,931 filed on 04/13/1999, 09/259,214 filed on 03/01/1999, and 08/910,798 filed on 08/13/1997.

Information Disclosure Statement

4. The information disclosure statements (IDS) submitted on 2/5/2001, 9/13/2002, 10/4/2002, 2/20/2003, 3/4/2003 are acknowledged. The submission is in compliance with the provisions of 37 CFR 1.97. Accordingly, the information disclosure statement is being considered by the examiner.

Drawings

5. The drawings have been reviewed and are objected under 37 CFR 1.84 or 1.152. See attached Notice of Draftsperson's Patent Drawing Review. Applicant is required to submit the drawing corrections within the time period set in the attached Office communication. See 37 CFR 1.85(a). Failure to take corrective action within the set period will result in ABANDOMENT of the application. In addition, if amendments to the specification are needed due to drawing corrections, Applicant is requested to submit such amendments while the case is being prosecuted to expedite the processing of the application.

Claim Objections

6. Claims 12-13 are objected to because they are partially drawn to non-elected inventions, i.e. plants and plant parts. For examination purposes, the instant claims will be interpreted as being directed to a plant cell modified to contain the expression system of claim 1 and a method to produce the polypeptide of SEQ ID NO: 2 in a plant cell. Appropriate correction is required.

7. Claim 9 is objected to due to the recitation of "PR protein PR-S". Abbreviations unless otherwise obvious and/or commonly used in the art, should not be recited in the claims without at least once reciting the entire phrase for which the abbreviation is used. It is suggested that the term be amended to recite "pathogenesis-related (PR) protein PR-S". Appropriate correction is required.

Claim Rejections - 35 USC § 112, Second Paragraph

8. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

9. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

10. Claim 1 (claims 2-13 dependent thereon) is indefinite in the recitation of "a recombinant expression system for processing a substantially pure enzyme comprising: (a) a host cell capable of expressing a first nucleotide sequence encoding a phytase....(b) a nucleotide sequence encoding said enzyme..." for the following reasons. As known in the art, a sequence is a graphical representation of the order in which nucleotides/amino acids are arranged in a molecule. Therefore, it is a polynucleotide, and not a sequence, what encodes a protein. In addition, the term "a first nucleotide sequence" is unclear since one cannot determine the meaning of "first" within the context of the claim and how it limits the scope of the claim. For examination purposes, it will be assumed that the claim is directed to a recombinant expression system comprising: (a) a host cell capable of expressing a polynucleotide which encodes the

polypeptide of SEQ ID NO: 2, and (b) a polynucleotide encoding the polypeptide of SEQ ID NO: 2 operably linked to a transcription control element operable in said host cell. Correction is required.

11. Claim 2 is indefinite in the recitation of "a transfer vector which comprises the expression system according to claim 1" as it is unclear how a vector can comprise a host cell. For examination purposes, it will be assumed that the claim is directed to a vector comprising a polynucleotide encoding the polypeptide of SEQ ID NO: 2. Correction is required.

12. Claim 8 is indefinite in the recitation of "wherein said first nucleotide sequence is preceded by a second nucleotide sequence encoding a signal peptide operably linked to said protein." for the following reasons. As indicated above, proteins are not encoded by sequences but rather by polynucleotides. In addition, the term "first nucleotide sequence is preceded by a second nucleotide sequence" is unclear and confusing. For examination purposes, it will be assumed that the claim is directed to the expression system of claim 1 wherein the polynucleotide encoding the polypeptide of SEQ ID NO: 2 further comprises a polynucleotide encoding a signal peptide which is operably linked to the polypeptide of SEQ ID NO: 2. Correction is required.

13. Claims 10-12 are indefinite in the recitation of "a ...cell modified to contain the expression system of claim 1". The expression system of claim 1 comprises a cell and a polynucleotide, therefore it is unclear as to how a cell can contain another cell. For examination purposes, claims 10-12 will be interpreted as being drawn to the host cell according to claim 1 wherein said cell is a prokaryotic cell, eukaryotic cell or a plant cell, respectively. Correction is required.

14. Claim 13 is indefinite in the recitation of "a method to produce a microbial phytase....which method comprises: (a) culturing....wherein said first nucleotide sequence is expressed; and (b) converting said plant.....into a composition suitable for animal feed" for the following reasons. The term "first nucleotide sequence is expressed" is unclear since as indicated above, one cannot determine how the term "first" limits the scope of the claim or what is its meaning within the context of the claim. Furthermore, as indicated above, a sequence is a graphical representation of a molecule, therefore it is a nucleic acid molecule, and not a sequence, which is expressed. Also, as indicated in the preamble, claim 13 is directed to a method to produce a microbial phytase, therefore it is unclear as to how step (b) is related to a method to produce a microbial phytase. For examination purposes, the claim will be interpreted as being directed to a method of producing a microbial phytase, said method comprising: (a) cultivating the plant cell of claim 12 under conditions suitable for the expression of the polynucleotide, and (b) isolating the microbial phytase of SEQ ID NO: 2. Correction is required.

Double Patenting

15. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

16. Claims 1-8, 10-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-9 of U.S. Patent No. 5876997. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 1 of the instant application is directed to a recombinant expression system which comprises a host cell and a polynucleotide encoding the polypeptide of SEQ ID NO: 2 wherein said polynucleotide is operably linked to a transcription control element operable in said host cell. Claim 2 is directed to a vector comprising a polynucleotide encoding the polypeptide of SEQ ID NO: 2. Claims 3-4 are directed to the expression system of claim 1 with the added limitation that the control element is a constitutive promoter or a tissue specific promoter. Claims 5-7 and 10-12 are directed to the expression system of claim 1 with the added limitations that the host cell is a prokaryotic, eukaryotic or a plant cell. Claim 8 is directed to the expression system of claim 1 with the added limitation that the polynucleotide encoding the polypeptide of SEQ ID NO: 2 further comprises a polynucleotide which encodes a signal peptide. Claim 13 is directed to a method of producing the polypeptide of SEQ ID NO: 2 by culturing a plant cell which comprises a polynucleotide

encoding the polypeptide of SEQ ID NO: 2. Claims 4-9 of U.S. Patent No. 5876997 are directed to an expression vector comprising a polynucleotide encoding the polypeptide of SEQ ID NO: 2, host cells transformed with said vector, and a method of producing the polypeptide of SEQ ID NO: 2 by culturing a host cell comprising said vector.

Since the recombinant expression system of claims 1, 5 and 10 of the instant application encompasses a host cell comprising a vector containing a polynucleotide encoding the polypeptide of SEQ ID NO: 2, claims 7-8 of U.S. Patent No. 5876997 would anticipate claims 1, 5 and 10, as written. In regard the limitations in claims 3-4, 6-8, 11-12, these are obvious over claims 7-8 of U.S. Patent No. 5876997 since one would use a specific promoter depending on the host cell being used, the level of expression desired and whether or not one would require controlled expression (i.e. inducible) or constitutive expression. Furthermore, the use of promoters is well known and they are widely used in the art. Similarly, the use of a eukaryotic or plant cell is also obvious over claims 7-8 of U.S. Patent No. 5876997 since the type of host cell used depends on whether cultivation of one type of cell is more cost-effective than another, the type of glycosylation desired, or the future use of the protein being expressed. Transformation of eukaryotic or plant cells is well known and widely used in the art. In regard to claim 8 of the instant application, this claim is also obvious over claims 7-8 of U.S. Patent No. 5876997 since one would use a signal peptide to secrete the protein to the extracellular medium for easier protein recovery. The use of signal peptides for protein secretion is well known and they are widely used in the art. The vector of claims 4-6 of U.S. Patent No. 5876997 would anticipate the vector of claim 2 of the instant application. The method of claim 13 is also obvious over claim 9 of U.S. Patent No. 5876997 since as indicated above, one would require the

use of a plant cell in the claimed method due to cost considerations, future applications of the product, or the type of glycosylation required. Therefore, for the reasons set forth above, claims 1-8, 10-13 of the instant application are either anticipated or would have been obvious over claims 4-6 of U.S. Patent No. 5876997.

17. Claims 1-8, 10-13 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 4-9 of U.S. Patent No. 6190897. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985). Although the conflicting claims are not identical, they are not patentably distinct from each other. Claim 1 of the instant application is directed to a recombinant expression system which comprises a host cell and a polynucleotide encoding the polypeptide of SEQ ID NO: 2 wherein said polynucleotide is operably linked to a transcription control element operable in said host cell. Claim 2 is directed to a vector comprising a polynucleotide encoding the polypeptide of SEQ ID NO: 2. Claims 3-4 are directed to the expression system of claim 1 with the added limitation that the control element is a constitutive promoter or a tissue specific promoter. Claims 5-7 and 10-12 are directed to the expression system of claim 1 with the added limitations that the host cell is a prokaryotic, eukaryotic or a plant cell. Claim 8 is directed to the expression system of claim 1 with the added limitation that

the polynucleotide encoding the polypeptide of SEQ ID NO: 2 further comprises a polynucleotide which encodes a signal peptide. Claim 13 is directed to a method of producing the polypeptide of SEQ ID NO: 2 by culturing a plant cell which comprises a polynucleotide encoding the polypeptide of SEQ ID NO: 2. Claims 4-9 of U.S. Patent No. 6190897 are directed to an expression vector comprising a polynucleotide encoding the polypeptide of SEQ ID NO: 2, host cells transformed with said vector, and a method of producing the polypeptide of SEQ ID NO: 2 by culturing a host cell comprising said vector.

Since the recombinant expression system of claims 1, 5 and 10 of the instant application encompasses a host cell comprising a vector containing a polynucleotide encoding the polypeptide of SEQ ID NO: 2, claims 7-8 of U.S. Patent No. 6190897 would anticipate claims 1, 5 and 10, as written. In regard the limitations in claims 3-4, 6-8, 11-12, these are obvious over claims 7-8 of U.S. Patent No. 6190897 since one would use a specific promoter depending on the host cell being used, the level of expression desired and whether or not one would require controlled expression (i.e. inducible) or constitutive expression. Furthermore, the use of promoters is well known and they are widely used in the art. Similarly, the use of a eukaryotic or plant cell is also obvious over claims 7-8 of U.S. Patent No. 6190897 since the type of host cell used depends on whether cultivation of one type of cell is more cost-effective than another, the type of glycosylation desired, or the future use of the protein being expressed. Transformation of eukaryotic or plant cells is well known and widely used in the art. In regard to claim 8 of the instant application, this claim is also obvious over claims 7-8 of U.S. Patent No. 6190897 since one would use a signal peptide to secrete the protein to the extracellular medium for easier protein recovery. The use of signal peptides for protein secretion is well known and

they are widely used in the art. The vector of claims 4-6 of U.S. Patent No. 6190897 would anticipate the vector of claim 2 of the instant application. The method of claim 13 is also obvious over claim 9 of U.S. Patent No. 6190897 since as indicated above, one would use of a plant cell for recombinant protein production due to cost considerations, future applications of the product, or the type of glycosylation required. Therefore, for the reasons set forth above, claims 1-8, 10-13 of the instant application are either anticipated or would have been obvious over claims 4-6 of U.S. Patent No. 6190897.

18. It is noted that the application Serial No. 10/430356, by inventors Short and Kretz, discloses a polynucleotide identical to that of SEQ ID NO: 1. Since application Serial No. 10/430356 is not available to the examiner at this time, no determination has been made as to whether or not a double patenting rejection should be applied to the claims of the instant application. If, upon availability of the above application to the examiner, it is determined that there are conflicting claims between application Serial No. 10/430356 and the instant application, double patenting will not be considered as new ground(s) of rejection.

Conclusion

19. No claim is in condition for allowance.

20. Applicants are requested to submit a clean copy of the pending claims (including amendments, if any) in future written communications to aid in the examination of this application.

21. Certain papers related to this application may be submitted to Art Unit 1652 by facsimile transmission. The FAX number is (703) 308-4556. The faxing of such papers must conform with

the notices published in the Official Gazette, 1156 OG 61 (November 16, 1993) and 1157 OG 94 (December 28, 1993) (see 37 CFR 1.6(d)). NOTE: If Applicant submits a paper by FAX, the original copy should be retained by Applicant or Applicant's representative. NO DUPLICATE COPIES SHOULD BE SUBMITTED, so as to avoid the processing of duplicate papers in the Office.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Delia M. Ramirez whose telephone number is (703) 306-0288. The examiner can normally be reached on Monday-Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy can be reached on (703) 308-3804. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

Delia M. Ramirez, Ph.D.
Patent Examiner
Art Unit 1652

DR
June 24, 2003

REBECCA E. PROUTY
PRIMARY EXAMINER
GROUP 1652